UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/823,188	03/29/2001	John Greeven	10004662-1	1218

7590 04/07/2005	EXAMINER	
HEWLETT-PACKARD COMPANY	SHAPIRO, JEFFERY A	

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ART UNIT	PAPER NUMBER
3653	

DATE MAILED: 04/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
Office Action Summary	09/823,188	GREEVEN ET AL.
	Examiner	Art Unit	
	Jeffrey A. Shapiro	3653	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>27 January 2005</u>.

2a)☐ This action is **FINAL.**   2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
    closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) <u>22,25-30,32-39 and 50-66</u> is/are pending in the application.

  4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) <u>22,25-30,32-39 and 50-66</u> is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

  a)☐ All   b)☐ Some * c)☐ None of:

    1.☐ Certified copies of the priority documents have been received.

    2.☐ Certified copies of the priority documents have been received in Application No. _____.

    3.☐ Copies of the certified copies of the priority documents have been received in this National Stage

       application from the International Bureau (PCT Rule 17.2(a)).

  * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
   Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413)
   Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/05 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 22, 24-30, 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff (US 6,471,089 B2) in view of Boyer (US 6,202,923 B1). Liff discloses the drug dispensing system as follows:

As described in Claims 22, 31, 32, 36, 53 and 54;

     a.   a controller (314);

     b.   a reservoir of pharmaceutical (20) *specific to an individual and to be dispensed over time to a patient, the pharmaceutical including at least one of tablets, liquids or gases, to be administered to a patient in individual or discrete doses according to a treatment regimen;* (See col. 1,

last line and col. 2, lines 1-7 for "dispensing a pharmaceutical over time"

and col. 8, lines 16-20 for liquid and other forms of drugs being dispensed.

See also col. 2, lines 52-54 which indicate that each bottle contains a

certain number of doses, which can be construed as including one dose or

a several doses. *Note that the reservoir can be construed as being*

specific to an individual, such as a doctor in a hospital or nurse, who can

either administer/manage the dispensing or who might outright own the

dispenser. Note also that an individual may be construed to be an

institution such as a pharmacy, research center or a hospital.)

c.   a drug delivery mechanism *located proximate to the patient at a*

location remote to a hospital (see figures 5-6c); (Note that the drug

delivery mechanism may be construed to be located proximate to a patient

in a hospital if that patient's room is located across from the dispenser for

the entire hospital. Note also that locating such a dispenser **in** all hospital

rooms could be construed to be no different than locating them across the

hall or down the hall, at the other end of the floor. The limitations

"proximate to the patient remote to a hospital" can be construed in a

reasonably broad sense to even include locating a dispenser, such as

Liff's element (20), at a bedside of a patient located **at their home**. If the

home is located next door to the hospital, it can be construed as remote

from the hospital. Note further, that such limitations as "*located*

proximate to the patient at a location remote to a hospital" are seen

as arbitrary to the function of the system, and that for all practical

purposes, Applicant's claimed system functions as Liff's system does.)

     d.   a data network interface coupled to said controller (see figure 13a);

As described in Claims 23, 24, 31-34, 37, 38 and 39;

     e.   sending messages to and from a health care service provider or

drug supplier (see figure 14T, for example, noting payors, doctors,

inventory and refills have files for information pertaining thereto),

     f.   said data message identifying the patient and the identity of the

particular drug (see figure 14K, for example);

     g.   dispensing the pharmaceutical to the patient from the reservoir in a

precise amount in response to signals from said controller; (Note that the

dispenser dispenses drugs in a wide variety of forms, such as bottles or

containers of pills, based upon signals from a controller, cited above.)

As described in Claims 25 and 55;

     h.   a human/display interface *including at least one of a tactile input*

device or a speech recognition device operatively coupled to the controller

(see figures 14A-14T, and 16, noting that laptop computers (566) and

workstation (555) inherently have, at the very least, either a keyboard or a

touchscreen—note also pen computers (558 and 568), which use a pen

for input);

As described in Claims 26, 27, 35 and 58;

       i.   effecting payment for the provision of health care service or for a

drug (see col. 18, lines 4-17);

As described in Claim 28;

       j.   the message is transported over the internet (see figure 18);

As described in Claim 29;

       k.   the message is transported via wireless (see col. 8, line 24;

As described in Claims 30, 57, 59, 60, 62 and 63;

       l.   a pharmaceutical level detector (182), see figure 7c;

       m.   the pharmaceutical level detector configured to ascertain at least

one of measured weight of pharmaceutical remaining in the reservoir,

decremented amount remaining in the reservoir, depth of measurement of

pharmaceutical in the reservoir, and static pressure within the reservoir

(note that the level detector (182) detects the level of the inventory

remaining in a reservoir, noting that "the reservoir" can be reasonably

broadly construed as being either a single dispensing device or several

dispensing devices, and that such a level of inventory is construed as

being a decremented amount, as the bottles of drugs are discrete items—

note also that it would have been obvious to one of ordinary skill in the art

to have detected static pressure in the reservoir, as static pressure

information is considered a functional equivalent of inventory level in

determining how full the reservoir is);

As described in Claim 48;

> n.   the pharmaceutical is at least one liquid material; (See col. 8, lines
>
> 16-20.)

As described in Claim 50;

> o.   the controller includes a memory device contained within the
>
> appliance (see Claim 30 of Liff et al, which states that a memory is
>
> connected to the system computer);

As described in Claim 51;

> p.   the memory device contains at least one treatment regimen
>
> regulating dispensing of individual doses of pharmaceutical to the patient;
>
> (see Claim 30 of Liff et al, which further states that the memory stores
>
> patient data and drug interaction data. See also col. 18, lines 42-65.)

Liff does not expressly disclose, but Boyer discloses a reservoir (22) for releasing

unpackaged doses of pharmaceutical (see col. 12, lines 5-30) to a patient configured to

contain a plurality of individual doses of unpackaged pharmaceutical by responding to

signals from a controller (83) through a data network (82, 84), wherein the intelligent

drug dispensing appliance (22) is sized and shaped for non-hospital placement

proximate to the individual patient. Note that the term bedside suggests that the dosage

releasing device can be placed at any bedside, for example, in a home or a hospital.

Note also that one ordinarily skilled in the art would recognize that it would be practical

to place the dispenser at a location where it is needed, of which the bedside of a patient

is just such a place. Note also that the system of Liff and Boyer works the same as
Applicant's system, whether or not it is located at the patient's bedside.

Both Liff and Boyer are analogous art because Liff discloses a hospital
management system controlling drug dispensers for packaged doses of pharmaceutical
and Boyer discloses a hospital management system controlling a drug dispenser for
unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in
the art to have used Boyer's dispenser of unpackaged doses of pharmaceutical in the
hospital management system of Liff.

The suggestion/motivation for doing so would have been to more efficiently
monitor and track unpackaged pharmaceutical doses dispensed by said devices as well
as to increase workflow and reduce errors. See Boyer, col. 4, lines 20-32. Note also
Liff at col. 1, lines 43-49, which indicates that decentralized unit-based dispensing
devices lowers costs relative to centrally located devices.

4.   Claims 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable
over Shusterman (US 6,471,087 B1) in view of Boyer. Shusterman discloses
Applicant's claimed system as follows.

    As described in Claim 53;

        q.   a controller (800) (See figure 8);

        r.   a reservoir of pharmaceutical specific to the individual patient to be

            dispensed over time (see col. 2, lines 23-36);

      s.   a drug dispensing mechanism (212), located proximate the patient

at a location remote to a hospital, the drug delivery mechanism coupled to,

and responsive to, the controller and to the reservoir to dispense the

pharmaceutical to the patient from the reservoir in a precise amount in

response to signals from said controller (again, note col. 2, lines 25-27,

which indicates that a precise dose of medication is stored in each

compartment for dispensing);

      t.   a data network interface (400) coupled to said controller (see col. 4,

lines 10-14);

As described in Claim 56;

      u.   at least one sensor (216, 218) operatively coupled to the controller,

the sensor capable of providing data signals indicative of the patient's

physical condition (see also figures 4b, 5, 6, 7);

Shusterman does not expressly disclose, but Boyer discloses a reservoir (22) for

releasing unpackaged doses of pharmaceutical (see col. 12, lines 5-30) to a patient

configured to contain a plurality of individual doses of unpackaged pharmaceutical by

responding to signals from a controller (83) through a data network (82, 84), wherein the

intelligent drug dispensing appliance (22) is sized and shaped for non-hospital

placement proximate to the individual patient. Note that the term bedside suggests that

the dosage releasing device can be placed at any bedside, for example, in a home or a

hospital.

Note also that one ordinarily skilled in the art would recognize that it would be

practical to place the dispenser at a location where it is needed, of which the bedside of

a patient is just such a place. Note also that the system of Shusterman and Boyer

works the same as Applicant's system, whether or not it is located at the patient's

bedside.   Both Shusterman and Boyer are analogous art because Shusterman

discloses a central controller (100) system controlling drug dispensers (see

Shusterman, figure 1 and col. 3, lines 65-67 and col. 4, lines 1-6) for packaged doses of

pharmaceutical and Boyer discloses a hospital management system controlling a drug

dispenser for unpackaged doses of pharmaceutical.

Both Shusterman and Boyer are analogous art because Shusterman discloses a

hospital management system controlling drug dispensers for packaged doses of

pharmaceutical and Boyer discloses a hospital management system controlling a drug

dispenser for unpackaged doses of pharmaceutical.

At the time of the invention, it would have been obvious to one of ordinary skill in

the art to have used Boyer's dispenser of unpackaged doses of pharmaceutical in the

hospital management system of Shusterman.

The suggestion/motivation for doing so would have been to more efficiently

monitor and track unpackaged pharmaceutical doses dispensed by said devices as well

as to increase workflow and reduce errors. See Boyer, col. 4, lines 20-32. Note also

Shusterman at col. 1, lines 19-38, which indicates that the medical profession

endeavors to reduce labor costs associated with large nursing staffs monitoring patients

by using accurate devices which remotely monitor drug dosage dispensing devices,

thereby allowing fewer staff to safely monitor more patients located at remote areas such as their home.

5.   Claims 65 and 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al in view of Boyer and further in view of Monkhouse et al (US 6,514,518 B2). Liff et al discloses the drug dispensing system as described above. Further, Liff includes the data network interface of Claim 66, as described previously. Liff et al does not expressly disclose, but Monkhouse discloses the following.

>   As described in Claim 65;
>
>   > v.   the drug delivery mechanism includes an ink-jet print head (22),
>   > (see col. 3, lines 6-57) capable of delivering precise amounts of the liquid
>   > (note that the "binder" is a liquid binder—see col. 5, lines 45-49);

At the time of the invention, it would have been obvious to one ordinarily skilled in the art to have coupled the ink jet printer drug dispensing device of Monkhouse et al to the networked system of Liff et al.

The suggestion/motivation would have been to provide drugs in a 3DP format, which provides a "multiphasic dosage form capable of providing delivery of multiple drugs having different release characteristics." See col. 2, lines 25-29 and col. 3, lines 5-17 of Monkhouse et al. See also Liff et al, abstract, noting that the system controls

dispensing of drugs from dispensers and that it would be obvious to one of ordinary skill

in the art to provide dispensers attached to Liff's system that would dispense drugs in a

standard format adopted by the medical community. 3DP format dosages are just such

a format.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liff et al

in view of Boyer and further in view of O"Brien (US 5,963,136). Liff et al discloses the

drug dispensing system as described above. Liff et al does not expressly disclose, but

O'Brien discloses the following.

As described in Claim 52;

w.   wherein the data network interface (see figure 3, for example,

noting that the system of O'Brien is a networked system—see also col. 8,

lines 19-24) is adapted to be removably coupled to (note that it would

have been expedient for one ordinarily skilled in the art to provide a

coupling that is readily removable, such as a plug or computer cable with

standard couplings, which are designed to be readily removable)

and receive information derived from at least one patient monitoring

sensor (see col. 5, lines 42-59, for example describing a temperature

sensor), such information being an appliance diagnostic status (note col.

5, lines 56-59 describe monitoring an electro cardiogram, which can be

construed as an appliance, the status of which would consist of the

electronic output of the monitor, since the purpose of the EKG monitor is

to provide diagnostic status of the patient, not necessarily the diagnostic

status of the monitor itself);

At the time of the invention, it would have been obvious to one ordinarily skilled in

the art to have coupled the networked prescription compliance system of O'Brien et al to

the system of Liff et al.

The suggestion/motivation would have been to provide "interactive prescription

compliance." See abstract of O'Brien et al. See also Liff et al, abstract, noting that the

system controls dispensing of drugs from dispensers in order to fill patient prescriptions

and that it would be obvious to one of ordinary skill in the art to provide a prescription

compliance capability to Liff's system, since patient compliance with a prescribed

regimen of drugs is considered by the medical community to be a major goal in

providing effective patient medical treatment.

Therefore, it would have been obvious to combine Liff et al, Boyer and O'Brien in

order to obtain the invention as described in Claim 49.

Response to Arguments

6.   Applicant's arguments with respect to Claims 22, 25-30, 32-39 and 50-66 have

been considered but are moot in view of the new ground(s) of rejection.

Boyer provides teaching for individual tablet dispensers to be used to dispense

bulk tablet pharmaceuticals. Boyer further teaches that this dispenser is digitally

controlled. Liff discloses a data network scheme of networking multiple pharmaceutical

dispensers. It would have been obvious at the time of the invention to have used Boyer's tablet dispenser in the system of Liff, as tablets are a recognized form of pharmaceutical which one ordinarily skilled in the art would want to provide to a system such as Liff's so as to dispense such drugs.

Again, Liff does not limit the pharmaceuticals it dispenses to packaged drugs, but also to broadly encompass any type of pharmaceutical dispenser one ordinarily skilled in the art would envision as being necessary to meet the needs of a typical healthcare system. Such a system would need capability to dispense bulk drugs, such as in tablet form. Additionally, such drug dispensing would need to be regulated as far as cost. Therefore, since Liff's system includes accounting and inventory algorithms, it would have been further recognizable to one ordinarily skilled to include bulk drug dispensers in Liff's system. The fact that Liff or any other of the cited prior art is for use with many patients, in a hospital or prison setting, or other setting is immaterial since these systems will still work the same as Applicant's claim limitations describe.
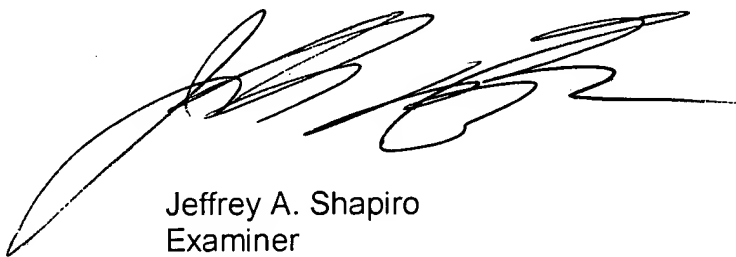
Therefore, as the claims read on the prior art, the rejection of Claims 22, 25-30, 32-39 and 50-66 is maintained.

7.   Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey A. Shapiro whose telephone number is (703)308-3423. The examiner can normally be reached on Monday-Friday, 9:00 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Donald P. Walsh can be reached on (703)306-4173. The fax phone number

for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

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you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey A. Shapiro
Examiner
Art Unit 3653

April 3, 2005

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